

Docket No. 33,383-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/806,370 Confirmation No.: 8568
Applicant : Holmes *et al.*
Filed : October 3, 2001
TC/A.U. : 1645
Examiner : V. Portner
Customer No. : 00270
Title : MUTANT CHOLERA HOLOTOXIN AS AN ADJUVANT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B is attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted with the appropriate fee of \$180.00 as set forth under § 1.17(p).

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Express Mail No. EU531733945US

REMARKS

Listed below is a co-pending US Patent application. This application and the present application are commonly owned:

- (1) U.S. Patent Application No. 10/478,308 filed December 4, 2003, now publication No. 2004/0176571 A1, published September 9, 2004.

The month of the publication for documents AU, AV, AAR, AAS, AAT, AAV, BR, BS, and BV could not be determined. The years of the publication for these documents are sufficiently earlier than the effective US filing date and/or foreign priority date of the present application so that the particular month of publication of these documents is not an issue (MPEP § 609.04(a)).

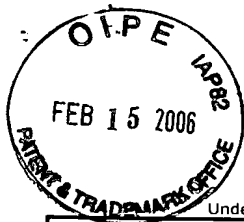
The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Respectfully submitted,

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Attorneys for Applicant

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PTO/SB/08A (07-05)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/806,370
				Filing Date	October 3, 2001
				First Named Inventor	Holmes
				Art Unit	1645
				Examiner Name	Portner, V.
Sheet	1	of	3	Attorney Docket Number	33,383-00

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,666,829	5/19/1987	Glenner <i>et al.</i>	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ -Kind Code ⁵ (if known)				
	AM	WO-99/27944	6/10/1999	Schenk		
	AN	WO-02/098368-A2	12/12/2002	Green <i>et al.</i>		
	AO	WO-02/098369-A2	12/12/2002	Green <i>et al.</i>		

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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				Examiner Name	Portner, V.
Sheet	2	of	3	Attorney Docket Number	33,383-00

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²	
	AS	AUDIBERT <i>et al.</i> , "Adjuvants: current status, clinical perspectives and future prospects", Immunology Today June 1993 14:281-284		
	AT	BAZIN <i>et al.</i> , "Predominant contribution of IgA antibody-forming cells to an immune response detected in extraintestinal lymphoid tissues of germ-free mice exposed to antigen by the oral route" J. Immunol. October 1970 105:1049-1051		
	AU	BRANDTZAEG <i>et al.</i> , "Immune functions of human nasal mucosa and tonsils in health and disease", in Immunology of the Lung and Upper Respiratory Tract, Bienenstock, J. (Ed.) McGraw-Hill, New York 1984 pp. 28		
	AV	BRANDTZAEG <i>et al.</i> , "Immunohistochemical characterization of local immunoglobulin formation in Crohn's disease of the ileum", Scand. J. Gastroenterol. 1976 11:447-457		
	AW	CRABBE <i>et al.</i> , "Antibodies of the IgA type in intestinal plasma cells of germfree mice after oral or parenteral immunization with ferritin", J. Exp. Med. October 1969 130:723-744		
	AX	CRAIG <i>et al.</i> , "Peyer's patches: an enriched source of precursors for IgA-producing immunocytes in the rabbit" J. Exp. Med. July 1971 134:188-200		
	AY	CUATRECASAS, P., "Gangliosides and membrane receptors for cholera toxin", Biochem. August 1973 12:3558-3566		
	AZ	GILL <i>et al.</i> , "ADP-ribosylation of membrane proteins catalyzed by cholera toxin: basis of the activation of adenylate cyclase", Proc. Natl. Acad. Sci. July 1978 75:3050-3054		
	AAR	GILL, D.M., "The arrangement of subunits in Cholera toxin", Biochem. 1976 15:1242-1248		
	AAS	HANSON, L.A., "Comparative immunological studies of the immune globulins of human milk and of blood serum", Intl. Arch. Allergy Appl. Immunol. 1961 18:241-267		
	AAT	HOLMES <i>et al.</i> , "Cholera toxin and related enterotoxins of gram-negative bacteria" in Handbook of Natural Toxins: Bacterial Toxins and Virulence Factors in Disease Vol. 8, Moss <i>et al</i> (Eds.) Marcel Dekker, Inc., New York 1995 pp. 225-255		
	AAU	HOLMES, R.K., "Heat-labile enterotoxins (Escherichia coli)" in Guidebook to Protein Toxins and Their Use in Cell Biology, Montecucco and Rappuoli (Eds.) Oxford University Press, Oxford, England 1997		
	AAV	JANEWAY and TRAVERS (Eds), "The Immune System in Health and Disease" in Immunobiology Second Edition, Current Biology Ltd., London, Great Britain 1996		
	AAW	JOBLING <i>et al.</i> , "Fusion proteins containing the A2 domain of cholera toxin assemble with B polypeptides of cholera toxin to form immunoreactive and functional holotoxin-like chimeras", Infect Immun. 1992 Nov, 60(11):4915-24		

Examiner Signature		Date Considered	
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Sheet	3	of	3
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NON PATENT LITERATURE DOCUMENTS

[illegible]

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